KLEAN 4 IN 1 HAND SANITIZER- alcohol gel DepilatoCosmetics SAS

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

KLEAN 4 IN 1 Hand Sanitizer

Active Ingredient(s)

Alcohol 80.16 % v/v. 73.68 % m/m Purpose: Antiseptic

Purpose

Topical Antiseptic

Use

Hand Sanitizer for the hygienic treatment of hands by friction. For use when soap and water unavailable.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

001 L (000 mL) NDC: 82122-005-01

KLEAN 4 IN 1 HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82122-005
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Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	73.68 g in 100 g

Inactive Ingredients

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Ingredient Name	Strength	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	0.35 g in 100 g	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.8 g in 100 g	
WATER (UNII: 059QF0KO0R)	24.68 g in 100 g	
METHYL GLUCETH-20 (UNII: J3QD0LD11P)	0.13 g in 100 g	
PEG-90 DIISOSTEARATE (UNII: YAE61SLW68)	0.25 g in 100 g	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.11 g in 100 g	

Packaging

# Item Code Package Description		Marketing Start Date	Marketing End Date
1 NDC:82122-005-01	857 g in 1 BOTTLE, PUMP: Type 0: Not a Combination Product	08/30/2021	

Marketing Information

That Rotting Times matter				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	08/30/2021		

Labeler - DepilatoCosmetics SAS (275215360)

Registrant - DepilatoCosmetics SAS (275215360)

Establishment

Name	Address	ID/FEI	Business Operations	
DepilatoCosmetics SAS		275215360	manufacture(82122-005)	

Revised: 8/2021 DepilatoCosmetics SAS